REMARKS

Upon amendment, claims 1-14 and 21-23 are pending.

Claims 15-20 are canceled without prejudice. Claims 21-23 are new and are directed to a methods of treatment covered by original claims 17-20. Claims 1 and 12 have been amended to recite "or a salt or tautomer" instead of "salts, hydrates and/or solvates and their tautomeric forms." Claim 1 has further been amended to delete from the definition of U "a group of the formula $-C(=O)-NR^e-OR^f$ wherein R^e and R^f independently from each other represent hydrogen or C_1-C_6-alkyl." Similarly Claim 12 has been amended to include the variable definitions from claim 1. Claims 2-11, 13 and 14 have been amended to more clearly define the claimed subject matter (i.e., to remove pluralities and multiple dependencies). Support for the new claims and the claim amendments can be found throughout the specification and in the claims as originally filed. No new matter has been added.

Applicants respectfully reserve the right to pursue any non-elected, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

Reconsideration and withdrawal of the objections to this application in view of the amendments and remarks herewith, is respectfully requested, as the application is in condition for allowance.

Objections to the Abstract.

The abstract has been objected to because "in chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use." Applicants respectfully feel that the abstract as originally filed satisfies the requirements for an abstract. That is, it is believed that the abstract enabled "the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure." (37 C.F.R. 1.72(b)). Nevertheless, applicants have amended the abstract to include formula (I) as well as to follow more closely with the language in the claims.

Lack of Unity

The Examiner has required restriction to one of the following:

I. Claims 1-20, drawn to compounds of Formulas (I) and (IA) in which A is phenyl, process for the preparation thereof, classified in class 544, subclasses 330, 331 and 332, pharmaceutical compositions and methods of treatment therewith, classified in class 514, subclass 269.

II. Claims 1-20, drawn to compounds of Formulas (I) and (IA) in which A is pyridyl, process for the preparation thereof, classified in class 544, subclasses 330, 331 and 332, pharmaceutical compositions and methods of treatment therewith, classified in class 514, subclass 269.

III. Claims 1-3, 6-11 and 13-20, drawn to all other Formula (I) compounds, process for preparation thereof, classified in class 544, subclasses 330, 331 and 332, inter alia, pharmaceutical compositions and methods of treatment therewith, classified in class 514, subclass 269, inter alia.

Applicants respectfully confirm the election of group I, with traverse.

Applicants respectfully request rejoinder and full examination of the compounds of groups I, II and III. In light of the core 3,4-dihydropyrimidin-2(1H)-one moiety present in each group, the search and examination of the compounds of group I would likely be co-extensive and, in any event, would involve such interrelated art that the search and examination of the both groups can be made without undue burden on the Examiner. As stated above, Original claims 1-20, in part, and new claims 21-23 read on the elected invention

Objectionable Claims

Claims 6-11 are objected to as being improper multiply dependent claims. As stated above, upon amendment, the claim dependencies of claims 6-11 have been corrected. Consideration of Claims 6-11 on the merits is respectfully requested.

Rejections under 35 U.S.C. § 101

Claims 17-19 are rejected under 35 U.S.C. 101, as allegedly lacking utility as being directed to a use without the setting forth of steps involved in the process. While Applicants strongly disagree with the Examiner's allegation, and solely for the purpose of advancing prosecution, claims 17-19 have been canceled without prejudice.

Applicants respectfully request that the rejections of the claims under 35 U.S.C. § 101 be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 20 is rejected under 35 U.S.C. 112, First Paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner states that the specification, while being enabling for in vitro and in vivo inhibition of neutrophil elastase in murine models, does not reasonably provide enablement for a process for controlling obstructive pulmonary disease, acute coronary syndrome, acute myocardial infarction or development of heart failure in humans and non-murine animals by administration of a neutophil elastase [NE] inhibitory amount of a compound of claim 1. While Applicants strongly disagree with the Examiner's allegation, and solely for the purpose of advancing prosecution, Claim 20 has been canceled without prejudice.

Claims 1-15 and 13-20 are also rejected under 35 U.S.C. 112, First Paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner states that the specification, while being enabling for Formula I and IA compounds and their salts and tautomeric forms, does not reasonably provide enablement for hydrates or solvates thereof. While Applicants strongly disagree with the Examiner's allegation, and solely for the purpose of advancing prosecution, claims 1 and 12 have been amended to recite or a salt or tautomer thereof. No new matter has been added by this amendment. Similarly, claims 15-20 have been canceled without prejudice.

Applicants respectfully request that all rejections of the claims under 35 U.S.C. § 112, First Paragraph be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 17-19 stood rejected under 35 U.S.C. 112, Second Paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim subject matter which applicant regards as the invention. While Applicants strongly disagree with the Examiner's allegation, and solely for the purpose of advancing prosecution, claims 17-19 have been canceled without prejudice.

Applicants respectfully request that the rejections of the claims under 35 U.S.C. § 112, Second Paragraph be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-5 and 12-20 are rejected under 35 U.S.C. 102(e), as allegedly anticipated by International Patent Application Publication No. WO 2004/024700 to Gielen-Haertwig (having the effective filing date of August 28, 2003) ("Gielen-Haertwig").

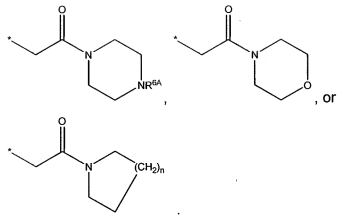
According to the Examiner, Gielen-Haertwig describes pyrimidinone compounds of Formula (I) in which each of the substituents encompass the substituents of the presently claimed compounds.

Applicants respectfully disagree.

Gielen-Haertwig and the instant claims share a similar structure and similar definitions for certain variables. However, Gielen-Haertwig and the instant claims are mutually exclusive at the definition of the variable R^6.

Gielen-Haertwig discloses:

> R^6 which represents hydrogen, C_1-C_6-alkyl, formyl, aminocarbonyl, mono-or di-C_1-C_4-alkylaminocarbonyl, C_3-C_8-cycloalkylcarbonyl, C_1-C_6-alkylcarbonyl, C_1-C_6-alkoxycarbonyl, N-(C_1-C_4-alkylsulfonyl)-aminocarbonyl, N-(C_1-C_4-alkylsulfonyl)-N-(C_1-C_4-alkyl)-aminocarbonyl, heteroaryl, heterocyclyl, heteroarylcarbonyl or heterocyclylcarbonyl or a moiety of the formula



As amended, the instant claims encompass:

R^6 which represents

– a group of the formula -T-U wherein

T represents a C_1-C_6-alkanediyl or C_2-C_6-alkenediyl group

and

U represents

- C_6-C_{10}-aryl or 5- or 6-membered heteroaryl each of which is substituted by one, two or three radicals independently selected from the group consisting of halogen, C_1-C_6-alkyl, 5- or 6-membered heteroaryl and a group of the formula -V-W wherein V represents a bond or a C_1-C_6-alkanediyl or C_2-C_6-alkenediyl group both of which can be further substituted by C_3-C_8-cycloalkyl, and W represents C_1-C_6-alkoxycarbonyl or hydroxycarbonyl,

- a group of the formula $-C(=O)-NR^a-SO_2-R^b$ wherein R^a represents hydrogen or C_1-C_6-alkyl, and R^b represents C_1-C_6-alkyl which can be substituted by trifluoromethyl, or R^b represents C_6-

C_{10}-aryl which can be substituted by C_1-C_6-alkyl, halogen, cyano, nitro or trifluoromethyl,

- a group of the formula -C(=O)–NR^cR^d wherein R^c represents hydrogen or C_1-C_6-alkyl, and R^d represents C_6-C_{10}-aryl which can be substituted by C_1-C_6-alkoxycarbonyl or hydroxycarbonyl,

  or

- C_6-C_{10}-arylalkoxy which, in the aryl part, can be substituted by halogen, C_1-C_6-alkyl, C_1-C_6-alkoxycarbonyl or hydroxycarbonyl,

or

R^6 represents

- C_3-C_8-cycloalkyl which can be substituted by up to three radicals independently selected from the group consisting of C_1-C_6-alkyl, hydroxy, oxo, C_1-C_6-alkoxy-carbonyl and hydroxycarbonyl,

- C_2-C_6-alkenyl which can be substituted by C_1-C_6-alkoxycarbonyl or hydroxy-carbonyl,

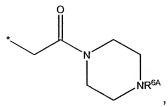
- C_1-C_6-alkyl or C_1-C_6-alkylcarbonyl which are substituted by C_1-C_6-alkoxycarbonyl-amino,

- C_3-C_6-alkoxycarbonyl which is substituted by phenyl-C_1-C_6-alkoxycarbonyl which for its part, in the phenyl moiety, can be further substituted by halogen, C_1-C_6-alkyl, C_1-C_6-alkoxycarbonyl or hydroxycarbonyl,

  or

- a group of the formula -SO_2–R^g wherein R^g represents C_1-C_6-alkyl which can be substituted by trifluoromethyl, or R^g represents C_6-C_{10}-aryl which can be substituted by C_1-C_6-alkyl, halogen, cyano, nitro, trifluoromethyl, C_1-C_6-alkoxy-carbonyl or hydroxycarbonyl,

The only groups disclosed by Gielen-Haertwig which comprise an alkanediyl or alkenediyl linker are compounds in which R^6 is substituted alkyl or



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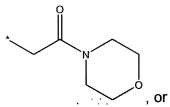

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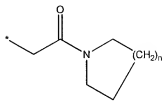

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Furthermore, when R^6 in Gielen Haertwig is alkyl, the optional susbstituents taught are aryl, heteroaryl, hydroxy, C_1-C_4-alkoxy, hydroxycarbonyl, C_1-C_6-alkoxycarbonyl, aminocarbonyl, mono- and di C_1-C_4-alkylaminocarbonyl, amino, mono- and di- C_1-C_4-alkylamino, C_1-C_4-alkylcarbonylamino, tri-(C_1-C_6-alkyl)-silyl, cyano, N-(mono-and di- C_1-C_4-alkylamino- C_1-C_4-alkyl)-aminocarbonyl. N-(C_1-C_4-alkoxy- C_1-C_4-alkyl)-aminocarbonyl and halogen.

None of these R^6 groups is encompassed by the instant claims. Indeed, none of the optional substituents, represent the claimed substituted aryl, substituted heteroaryl, -C(=O)–NR^a–SO_2–R^b, -C(=O)–NR^cR^d or C_6-C_{10}-arylalkoxy groups bound to the alkanediyl.

Furthermore, none of the other R^6 groups of Gielen Haertwig represent the C_3-C_8-cycloalkyl, C_2-C_6-alkenyl, C_1-C_6-alkoxycarbonyl-amino substituted C_1-C_6-alkyl, C_1-C_6-alkoxycarbonyl-amino substituted C_1-C_6-alkylcarbonyl, phenyl-C_1-C_6-alkoxycarbonyl substituted C_3-C_6-alkoxycarbonyl, or -SO_2–R^g groups encompassed by the instant claims.

As such, Gielen-Haertwig does not teach or disclose compounds, compositions, methods or process encompassed by the amended claims and thus does not anticipate the instant invention.

Applicants respectfully request that the rejections of the claims under 35 U.S.C. § 102, be withdrawn.

Double Patenting Rejections

Claims 1-5 and 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 if United States Patent Application Serial No. 10/527,391.

As it remains unknown what subject matter claimed and disclosed in the present application will be deemed allowable, any statement regarding the provisional rejection made would be premature. Therefore, Applicants respectfully traverse this rejection and request that this rejection be held in abeyance until claimed subject matter is deemed allowable in the application.

CONCLUSION

In view of the amendments and remarks made herein, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105.

Date: September 4, 2008

Respectfully Submitted,

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